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Proposed Maximum Residue Limit PMRL2014-02

Fludioxonil

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on potatoes and sweet potatoes to the product label of Stadium Fungicide, containing technical grade azoxystrobin, difenoconazole and fludioxonil is acceptable. The specific uses approved in Canada are detailed on the label of Stadium Fungicide, *Pest Control Products Act* Registration Number 31050.

The evaluation of this fludioxonil application indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for fludioxonil is being conducted via this document (see Next Steps, the last section of this document). MRL consultation for the other active ingredients, azoxystrobin and difenoconazole, present in Stadium Fungicide are being conducted under separate actions. A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace MRLs already established for fludioxonil, are as follows.

Table 1 Proposed Maximum Residue Limits for Fludioxonil

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	6.0	Tuberous and corm vegetables (Crop Subgroup 1C; except true yam tubers)[2]

1 ppm = parts per million

2 The MRL is proposed to replace the currently established 0.02 ppm for potatoes and of 3.5 ppm on Tuberous and corm vegetables except potato (Crop Subgroup 1D), except true yam tubers for which an MRL of 8.0 ppm is currently established.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for fludioxonil in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Tuberous and corm vegetables (Crop Subgroup 1C)	6.0 (except true yam tuber)	6.0 (except true yam tuber)	0.02 (potatoes) 10 (sweet potatoes)
True yam tuber	8.0	8.0	10

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fludioxonil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Previously reviewed residue data from field trials conducted in/on potatoes (postharvest) were reassessed in the framework of this petition. In addition, a processing study in treated potatoes was also reassessed to determine the potential for concentration of residues of fludioxonil into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for fludioxonil was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL(s) for Tuberous and corm vegetables (Crop Subgroup 1C), except true yam tubers.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Potatoes	Postharvest spray 0.44–0.50	0	0.53	3.35	No concentration observed

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fludioxonil. Residues of fludioxonil in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.